

Injectomat® Agilia

Technical Manual



**FRESENIUS
KABI**

Introduction

General introduction

The **Injectomat Agilia** syringe pump is intended for the infusion of intravenous agents with a low flow rate. Its potentiometric sensor will detect the diameter of the syringe installed to +/- 1.5 mm and propose the last selected syringe in this range.

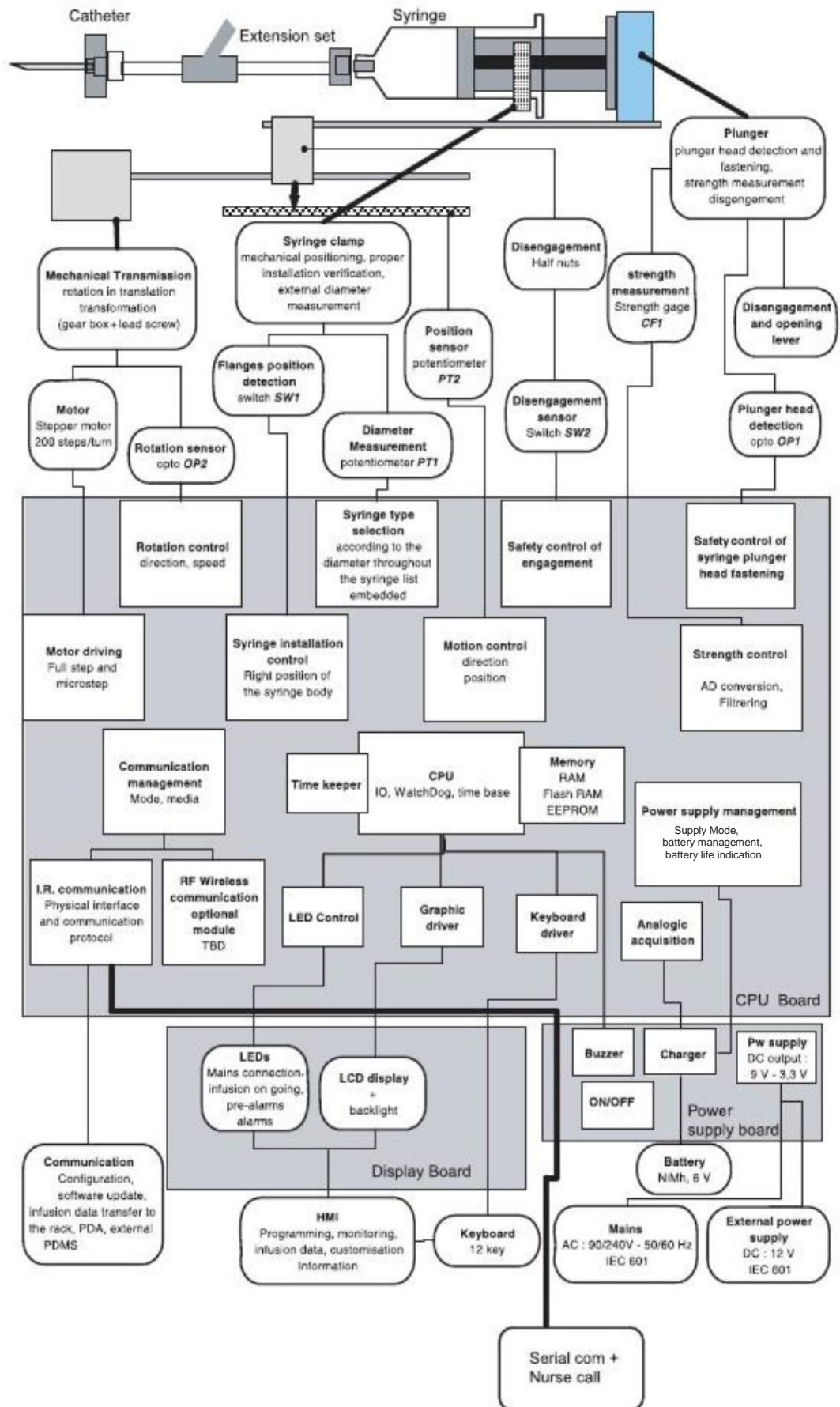
Injectomat Agilia propose up to 50 different brands and types of syringes in sizes of 50/60 ml, 30ml, 20ml, 10ml and 5ml.

Injectomat Agilia has a range of flow rates from 0.1 to 1200 ml/h according to the diameter of the selected syringe. It is the ideal device for intensive care units and neonatology.

Injectomat Agilia is fitted at the back with an infrared cell. **Fresenius Kabi** uses a **Link+ Agilia** rack system enabling several Agilia IV pumps to communicate through a communications system via the infrared cell and rack.

Injectomat Agilia is equipped with an integrated system allowing it to be fixed onto a pole or a rail. Its integrated locking system allows three Agilia IV pumps to be stacked on top of one another to facilitate transportation.

Operation diagram



Precautions for use

Fresenius Kabi recommend a complete reading of the Instructions For Use manual, in accordance with norm EN 60 601-1.



Fresenius Kabi cannot, in any circumstances, be held responsible for any medical or other problem due to incorrect use of the device.

Kindly consult the Instructions For Use manual for more details.

Temperature: 5°C to 40°C / 41°F to 104°F.

Humidity: 20% to 90%, no condensation.

Atmospheric pressure: 700hPa to 1060hPa.

Operation safety

As soon as it is in operation, the **Injectomat Agilia** syringe pump ensures continuous surveillance of its functions. Any internal fault or any procedural anomaly is immediately detected. Nevertheless, abnormal functioning of the device, without a defined cause, must always be brought to the attention of the qualified staff in your establishment or our Technical Service.

On the first occurrence of a fault, an alarm is triggered for any $\pm 5\%$ flow rate difference in relation to normal flow rate.

A second check activates an alarm when there is a 1ml discrepancy in relation to the predicted infused volume or when a flow rate discrepancy of $\pm 20\%$ is identified. The alarm for the most rapidly detected discrepancy is activated.

Injectomat Agilia is equipped with an internal battery that ensures normal functioning during a mains power cut. In addition, a safety fuse protects the concerned mains area.

Technical characteristics

Electrical details

Power supply: 100V-240V~/ 50-60Hz with functional Earth

Max. consumption: 180mA

Max. power: 15VA

Fuse: T1AH 250V internal to power supply unit

Battery: 6V-1.8Ah. (NIMH)

External power supply: 9VCC. Power > 15Watts.

Electronic details

The **Injectomat Agilia** contains 3 electronic boards:

Power supply board

CPU board

Display board.

Mechanical details





Dimensions: H x L x W: 135 x 345 x 160 mm

Weight: approximately 2.1kg.

Material characteristics

	Components	Materials
1	Syringe barrel clasp	Polyamide
2	Syringe flange cradle	POM
3	Pusher	Polyamide
4	Pusher protector	ABS
5	Handle	Stainless steel
6	Assembly bolt	POM
7	Infrared cell	Polycarbonate
8	Fixing clamp	Aluminium + epoxy
9	Fixing button	POM + PA
10	Mains connection	Thermoplastic
11	Communication port and 12-15 Vdc power	Stainless steel
12	Mains warning	Polyester
13	Screen	PC
14	Silence Alarm	Polyester
15	ON/OFF	Polyester
16	Bolus or Prime	Polyester
17	Value selection	Polyester
18	Value selection	Polyester
19	Value selection	Polyester
20	Value selection	Polyester
21	Functioning, pre-alarm and alarm warnings	Polycarbonate
22	Validation	Polyester
23	Stop: infusion stop	Polyester
24	Menu / Exit	Polyester
25	Battery door	ABS
26	Housing	ABS
27	Feet and membranes	Silicone

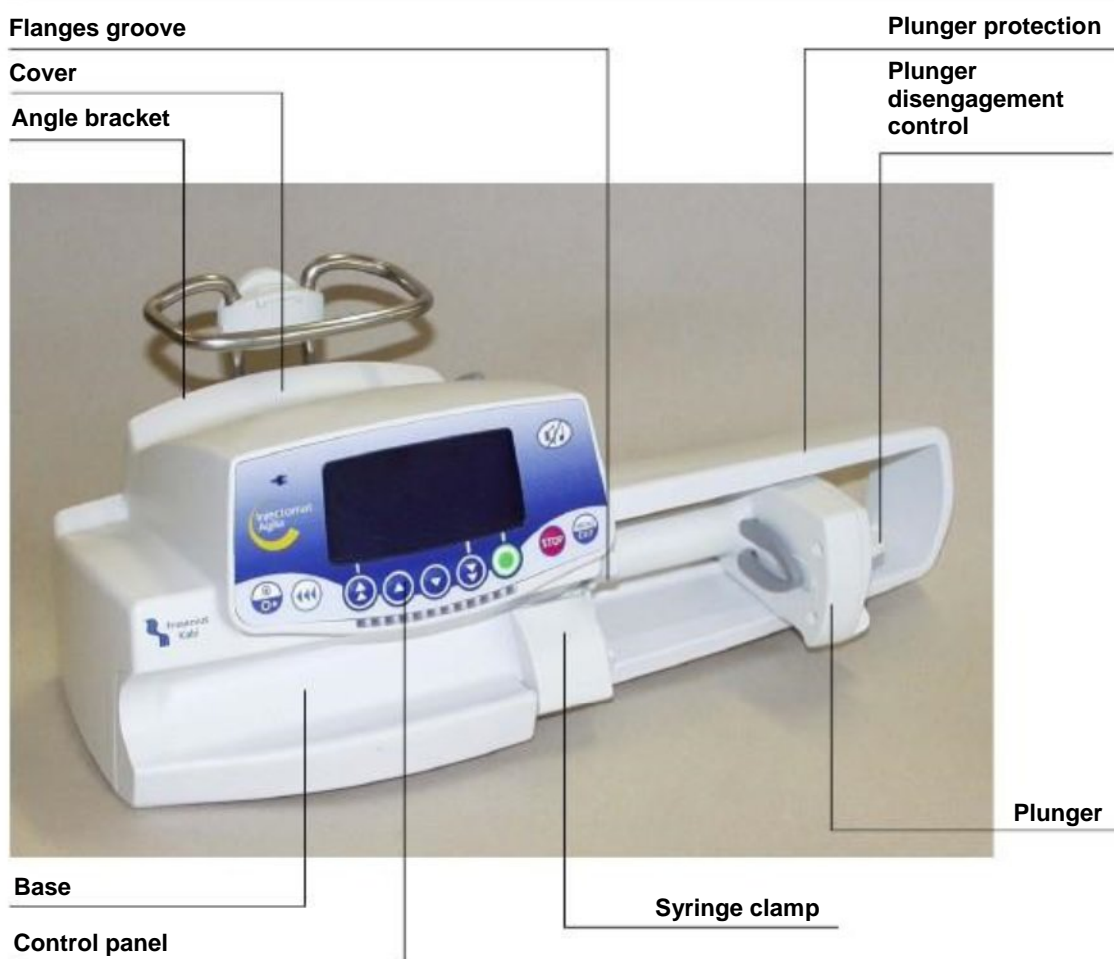
Conformity and norms

 0459	Conform to the 93/42/CE Medical Directive.	IP22 Protection against splashing liquid.
Safety of Electro Medical Equipements	Conform to EN/IEC 60601-1 and EN/IEC 60601-2-24	 Protection against leakage current: Defibrillation-proof type CF applied
EMC (ElectroMagnetic Compatibility)	Conform to EN/IEC 60601-1-2 and EN/IEC 60601-2-24	 Protection against electric shocks: class II. Functional earth. 



Description and operation

Physical description



Injectomat Agilia is made up of three main parts: a base, a cover and an angle bracket.

The cover contains:

- a display board.

The base contains:

- a CPU board

- a mechanical framework assembly

- a plunger unit.

The angle bracket contains:

- a power supply board and a battery

- Fixing clamp system.

Preventive maintenance

Recommendations

The device can only be checked, serviced or repaired by Fresenius Kabi or by a certified and approved maintenance service. Any abnormal functioning of the pump must be brought to the attention of your in house qualified technical personnel or our Technical Service.

Should you need to return the pump to our Technical Service, it should be cleaned, disinfected and very carefully packaged, preferably in its original packaging, before being shipped.

For all information concerning the repair and use of the pump, kindly contact our Technical Service or our Customer service.

Fresenius Kabi is not liable for loss or damage to the pump during its transport to our Technical Service.

Maintenance schedule

Preventive maintenance

In order to maintain the pump's performances, a preventive maintenance inspection must be carried out every 3 years. This procedure, which includes battery replacement, should be carried out by a qualified technician.

Any abnormal functioning or failure must be reported to the qualified technical staff in your organisation or to our Technical Service. In these instances, the pump should not be used.



Important:

If these maintenance procedures are not observed, the pump correct operation will be impaired.

Quality control

At the request of the health organisation, a quality check will be carried out every 12 months.

A quality check (not included in the guarantee) consists of different inspection procedures as defined in the pump Technical Manual. Only a qualified technician may perform the quality check which must be performed using Fresenius Kabi software.

For more information, kindly contact our Technical Service.



Recycling of obsolete batteries and devices :

Before disposal, remove battery from the device. Batteries and devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulations. For further information pertaining to waste processing regulation, contact your local Fresenius Kabi.












Checks

A quality control certificate is available at the end of this section.



In order to ensure the smooth running of the checking procedure, recharge the battery for 16 hours beforehand.

Keyboard description.

Key	Function
	ON switches on the pump. OFF switches it off when pressed for over three seconds.
	SILENCE ALARM
	STOP stops infusion.
	Menu/Exit accesses the tests menu.
	The selection keys scroll through the numbers and letters on the tenths, units and tens values and allow one to move to the next menu.
	OK validates your test selection or moves the cursor. enter starts up infusion. exit exits the screen and returns to the "previous" menu.
	starts or stop prime ; starts or stops bolus

Cleaning and disinfecting

The device is part of the patient immediate environment. It is advisable to clean and disinfect the device external surfaces regularly and especially before connecting a new patient and before any maintenance operation in order to protect patient and staff.

Disconnect the device from its main supply before cleaning.

Do not place in an AUTOCLAVE nor IMMERSE the device. Do not let liquids enter the device housing.

If the device is placed in a high contamination risk unit, it is advisable to leave it in the room during disinfecting, after having disinfected it with moist cloth.

Use a cloth soaked in DETERGENT-DISINFECTANT, previously diluted with water if required, to destroy micro organisms.

Avoid abrasive scrubbing which could scratch the casing.

Do not rinse or wipe the surfaces.



Do not use :

TRICHLOROETHYLENE-DICHLOROETHYLENE.

AMMONIA.

AMMONIUM CHLORIDE.

CHLORINE AND AROMATIC HYDROCARBON.

ETHYLENE DICHLORIDE-METHYLENE.

CHLORIDE-CETONE.

These aggressive agents could damage plastic parts and cause device malfunction.



Take care with ALCOHOL based SPRAYS (20% - 40% alcohol). They lead to tarnishing and small cracks in the plastic, and do not provide the necessary cleaning prior to disinfection.

Disinfecting SPRAYS may be used, in accordance with the manufacturer recommendation, from a distance of 30cm of the device, avoid the accumulation of the product in liquid form.

Please contact the appropriate service responsible for cleaning and disinfecting products in your establishment for further details.

Storage

The device should be stored in a dry, cool place.

In case of prolonged storage, the battery should be disconnected via the battery access flap situated underneath the device. This should be done by a qualified technician.

Storage conditions and carrying:

Temperature: -10°C to 60°C / 14°F to 140°F.

Atmospheric pressure: 500hPa to 1060hPa.

Humidity: 10% to 90%, no condensation.

Fully recharge the battery before using the device to avoid any risks caused by micro power

Use of the internal battery

This device is provided with NiMH battery.

When the device is disconnected from the mains, it automatically switches to battery mode.

Before starting for the first time, charge the battery for approx. 5 hours by connecting the power supply cord without using the device.

The maximum battery life is achieved after several charge/discharge cycles.

In case of frequent mains operations, battery life may be decreased. To limit this risk, it is recommended to use the device on the battery mode, approximately every 4 weeks, until getting a battery pre-alarm signal.

Diagnostic

Troubleshooting guide

Problem	Cause	Action
End of infusion detected too early (at approximately 10ml). No end of infusion pre-alarm and alarm	The installed syringe doesn't correspond with the selected syringe.	Replace or confirm the right syringe brand. Recalibrate the position sensor (Cal 3) with maintenance software.
Flow rate or displacement control drift.	The installed syringe doesn't correspond with the selected syringe. The position sensor calibration values have drifted.	Replace or confirm the right syringe brand. Check the position sensor calibration values and recalibrate it if necessary. Change the position sensor.
Occlusion alarm after the device has been turned on.	Wrong calibration of the force sensor. Force sensor is out of order. Flexible circuit cut.	Recalibrate and check the force sensor. Replace the force sensor. Replace the flexible circuit.
Occlusion alarm during the infusion.	The pressure limit selected is too low. Wrong calibration of the force sensor. Flexible circuit cut.	Select a higher pressure limit. Recalibrate and check the force sensor. Replace the flexible circuit.
Disengagement alarm after the device has been turned on or during the infusion.	The disengagement micro-switch is defective. Carriage flexible circuit is cut.	Replace the micro-switch. Replace the flat ribbon cable.
Unjustified alarm of plunger head position.	Optical switch and/or anti-siphon arm finger detection are defective. Flexible circuit cut.	Check the anti-siphon system Check the good condition of the pusher internal mechanism. Replace the flat ribbon cable.
Unjustified alarm of syringe holder and/or syringe body.	Defective syringe holder potentiometer. Flat ribbon cable is defective. Switch and /or flat ribbon cable flanges detection are defective.	Check the syringe holder and replace the defective parts if necessary.
Display defect: LED, screen.	Control transistors, LED and/or connections are defective.	Check the good condition of the display board. Replace the LED or the control transistors. Check the connectors linking the CPU and display boards. Replace the display board.
Device turns off when mains cord disconnection.	The battery is unplugged or the battery cable is cut.	Check the battery connection.
The power supply LED doesn't lit.	Battery is totally discharged. Power supply board is defective.	Replace the battery. Replace the power supply board.

Problem	Cause	Action
Battery alarm while it has been completely charged.	<p>MAX 4376 voltage regulator is out of order.</p> <p>Battery is totally discharged.</p>	<p>Check the battery charging voltage</p> <p>Replace the power supply board if necessary.</p> <p>Replace the battery.</p>
The device turns ON or turns OFF alone.	<p>Defective keyboard.</p> <p>Power supply board is out of order.</p>	<p>Check and replace the keyboard if necessary</p> <p>Replace the power supply board and check secondary μC functionality.</p>
Some keys of the keyboard do not work.	Defective keyboard.	Check and replace the keyboard if necessary.
After a fall	Mechanical elements are damaged.	Check the status of the housings and the mechanical system.

Useful addresses

CUSTOMER SERVICE

Fresenius Vial
Le Grand Chemin, 38590 Brézins

Tel.: 33 (0) 4 76 67 11 11
Fax: 33 (0) 4 76 67 11 34

TRAINING DEPARTMENT / TECHNICAL DEPARTEMENT

Fresenius Vial
Le Grand Chemin, 38590 Brézins

Tel. : 33 (0) 4 76 67 10 76
or 33 (0) 4 76 67 11 40
or 33 (0) 4 76 67 60 73
Fax : 33 (0) 4 76 67 11 22

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Design and construction : SEDOC



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